SEP 3 0 2003

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Special 510(k)
CORRECTIVE ACTION BEING EFFECTED
SAFETY AND EFFECTIVENESS SUMMARY

SurgASSIST *Circular Stapler Digital Loading Units®*

In Accordance with 21 CFR section 807.92 Power Medical Interventions, Inc., is submitting the following safety and effectiveness summary.

1) Submitter Information:

Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938
267-775-8151 Ph
267-775-8123 Fax

Applicant: Barbara J. Whitman

Date of Notification: August 29, 2003

2) Name of Device:

Trade Name: SurgASSIST™
Circular Stapler DLUs
21 mm, 25 mm, 29 mm, 33 mm

Common Name: Circular Stapler with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

A. SurgASSIST™ System with Circular Stapler Digital Loading Units®, (21 mm, 25 mm, 29 mm, 33 mm), with Titanium Implantable Staple, Power Medical Interventions, Inc., New Hope, PA. REF CS21, CS25, CS29, CS33 (K003277).

B. Endopath ILS Endoscopic Circular Staplers, 21 mm, 25 mm, 29 mm, 33 mm, Ethicon Endo-Surgery, Cincinnati, OH. (K920752).

4) Device Description:

The SurgASSIST™ System with Circular Stapler Digital Loading Units® (DLUs) offers computer mediated steering and stapling. The DLUs contain implantable, titanium staples and integral cutting blades. The DLUs are used to anastomose tubular structures by applying a double staggered circular row of staples through the tissue. The staples form to controlled closed conditions to secure the layers of tissue together. The DLUs also cut away the excess tissue at a controlled diameter inside the ring of staples. The Circular Stapler DLUs are available in the following four sizes: 21 mm, 25 mm, 29 mm, and 33 mm. The DLU is supplied sterilized and ready for use upon removal from its packaging.

5) Device Modification

Modifications were made to the predicate SurgASSIST™ Circular Stapler Digital Loading Units® (originally cleared under K003277) to address the root cause of the voluntary recall, which was a potential for latching mechanism failure, which could result in staple line failure and/or anvil jam. In order to further minimize the already low risk of latching mechanism failure, the spline tube and trocar were modified to improve engagement of the latch fingers. Further details of this modification can be found in Section H of this submission, under the "Device Modification" heading.

6) Indications For Use

The SurgASSIST™ Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

7) Comparison to Predicate Devices

The following table compares the subject Circular Stapler to the previously cleared predicates, Circular Stapler Cutter Digital Loading Units® (K003277) and Endopath ILS Endoscopic Circular Staplers (K920752).

Circular Stapler DLU Product Features Comparison Chart

Features & Description	**SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs)** 21 mm, 25 mm, 29 mm, 33 mm REF: CS21, CS25, CS29, CS33	**Predicate** **SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs)** 21 mm, 25 mm, 29 mm, 33 mm	**Predicate** **Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler** 21 mm, 25 mm, 29 mm, 33 mm
Name	Circular Stapler Digital Loading Units® 21 mm, 25 mm, 29 mm, 33 mm	Circular Stapler Digital Loading Units® 21 mm, 25 mm, 29 mm, 33 mm	Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler 21 mm, 25 mm, 29 mm, 33 mm
Manufacturer of Record	Power Medical Interventions, Inc.	Power Medical Interventions, Inc.	Ethicon Endo-Surgery, Inc
Contract Manufacturer	Lacey Manufacturing Bridgeport, CT	Lacey Manufacturing Bridgeport, CT	Ethicon Endo-Surgery, Inc
510(k) Clearance Numbers	Subject of this Notification	K003277	K920752
Intended use	Applications throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.	Applications throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.	Applications throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.
Contraindications	Same, refer to labeling	Same, refer to labeling	Same, refer to labeling
FDA Class (System)	II	II	II
Sizes	21 mm, 25 mm, 29 mm, 33 mm Circular Staplers	21 mm, 25 mm, 29 mm, 33 mm Circular Staplers	21 mm, 25 mm, 29 mm, 33 mm Circular Staplers
Staple Shape	B-Shaped	B-Shaped	B-Shaped

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Circular Stapler DLU Product Features Comparison Chart

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Features & Description	**SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs)** 21 mm, 25 mm, 29 mm, 33 mm REF: CS21, CS25, CS29, CS33	**Predicate** **SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs)** 21 mm, 25 mm, 29 mm, 33 mm	**Predicate** **Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler** 21 mm, 25 mm, 29 mm, 33 mm
Closed Staple Height	Approximately 1.5 mm – 2.3 mm	Approximately 1.5 mm – 2.3 mm	1.0 mm – 2.5 mm
Staple Material	ASTM F-67 Unalloyed Titanium	ASTM F-67 Unalloyed Titanium	ASTM F-67 Unalloyed Titanium
Knife Material	Stainless steel	Stainless steel	Stainless steel
DLU Materials	Polymeric materials, surgical grade stainless steels, adhesives, and lubricants	Polymeric materials, surgical grade stainless steels, adhesives, and lubricants	Polymeric materials, surgical grade stainless steels, adhesives, and lubricants
Cutting Mechanism	Circular Knife	Circular Knife	Circular Knife
DLU Internal Power	None	None	None
Power	Electrically powered via a remote Power Console	Electrically powered via a remote Power Console	Manually powered
Software containing	Yes	Yes	No
Digital Information	Memory module containing digital data for identification, etc.	Memory module containing digital data for identification, etc.	None
How Supplied	Sterile - Single Patient Use	Sterile - Single Patient Use	Sterile – Single Patient Use

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Circular Stapler DLU Product Features Comparison Chart

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Features & Description	**SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs)** 21 mm, 25 mm, 29 mm, 33 mm REF: CS21, CS25, CS29, CS33	**Predicate** **SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs)** 21 mm, 25 mm, 29 mm, 33 mm	**Predicate** **Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler** 21 mm, 25 mm, 29 mm, 33 mm
Safety Mechanism	Will not deploy until within an appropriate range for desired closed staple height	Will not deploy until within an appropriate range for desired closed staple height	Contains indicators for appropriate range for desired closed staple height, but can be deployed out of range
Insertion Mechanism	Flexible, steerable	Flexible, steerable	Rigid
Method of Sterilization	Ethylene Oxide Gas (ETO)	Ethylene Oxide Gas (ETO)	Irradiation
Packaging	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 0 2003

Ms. Barbara J. Whitman
Regulatory Affairs Manager
Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, Pennsylvania 18938

Re: K032701
Trade/Device Name: SurgASSIST™ Circular Stapler Digital Loading Units®
21mm, 25mm, 29mm, 33mm
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: August 29, 2003
Received: September 2, 2003

Dear Ms. Whitman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) No. K Ø32741

Device Name: *SurgASSIST™*
Circular Stapler
Digital Loading Units®
21 mm, 25 mm, 29 mm, 33 mm

INDICATIONS FOR USE:

The SurgASSIST™ Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use X OR Over-The-Counter Use _____
Per 21CFR §801.109

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032701